UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trad mark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/488,298	01/20/00	LUTZ O	3874-128 US

HM12/0822

Mary Kakefuda Esq.
Mathews Collins Shepherd & Gould P.A.
100 Thanet Circle
Suite 306
Princeton NJ 08540

EXAMINER	
KIM,J	
ART UNIT	**PAPER NUMBER**
1617	9

DATE MAILED: 08/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/488,298	LUTZ ET AL.	
	Examiner	Art Unit	
	Jennifer M Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5 and 7-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5,7-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Response to Amendment

The amendment filed 06/06/2001 has been entered. Claims 1,4,5 and 7-21 have been amended. New claims 21-24 have been added. Claims 2,3 and 6 have been canceled.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 4-5, and 7-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amselem of record and Brandely et al. of record, for the reasons set forth in the office action mailed 12/04/2000.

Applicants arguments filed 06/06/2001 have been fully considered but they are not persuasive. Applicants argue that the present claims is not anticipated by Amselem since Amselem does not teach or suggest a fluid pharmaceutical composition comprising an aqueous dispersion of micelles having an average diameter of less than about 300 nm. This is not persuasive since dosage formulation of pharmaceutical composition from solid to liquid etc. and optimizing particle size for absorption of active

agents are obvious since it is well within the knowledge of skilled artisan. The skilled artisan would have been motivated to further convert well known Amselem's solid micelle formulation into liquid micelle formulation since liquid formulation has advantages over the solid formulation in that it is easy to titrate appropriate specific dosages for the elderly and children and it is easy to swallow for those patients who have trouble swallowing a solid dosage form.

Applicants further argue that Brandely et al. do not teach or suggest a fluid pharmaceutical composition comprising an aqueous dispersion of micelles having an average diameter less than about 300nm. Mover over, with regard to claim 11, Amselem describes a weight percentage in a solid wherein in the present invention the weight percentage is determined in a liquid therefore, the range of concentration of TPGS in the Amselem composition is different than the range of concentration of TPGS.

This is not persuasive since Brandely teaches polypeptide having same utility as composition of Amselem in treatment of cancer. Therefore, with regard to claims 8 and 17, it would have been obvious to skilled artist to incorporate polypeptide into Amselem's composition to treat cancer. The motivation for combining the components flows from their individually known common utility (see In re Kerkhoven, 205 USPQ 1069(CCPPA 1980)). The determining proportions of active agents to be used in convertion of solid to liquid pharmaceutical formulation, is deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations.

Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

It is suggested, to advance the prosecution of the subject application, that a side-by-side comparison with prior art composition be performed and results submitted per Rule 1.132 for review by the Patent Office.

In view of the above Office Action of 12/04/2000 is deemed proper and asserted with full force and effect herein to obviate applicant's claims.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1,4-5, and 7-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amselem (U.S.Patent No 5891469) and Brandely et al.(1991:663504).

Amselem at the abstract, column 3, lines 60-65, column 4, lines 7-16, and lines 55-60, column 5, lines 31-43, lines 55-58, column 6, lines 9-20, column 13, Example 11, and column 14, claims 13, 20, and 22, teaches Applicants' claimed composition use for treating mammal with various diseases.

Amselem teaches at column 3, lines 17-22, column 4, lines 7-13, and column 14, claim 12, teach the anticancer drug etoposide comprising surfactants such as tocoferol(TPGS), dispersion adjuvant(PVP) and a hormone in a micelle formulation.(See claims 9, 14-16, and 21).

Amselem also teaches at column 6, lines 43-48, teach the range of TPGS set forth in claim 11 and applicants upper range of TPGS set forth in claims 12-13.

Brandely et al. at the title, teach the use of polypeptide in a pharmaceutical composition for the treatment of cancer.

The difference between applicants' invention and the primary reference is that lack of polypeptide and a peptide set forth in claims 8 and 17.

However, as stated in In re Kerkhoven, 626 f.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980):

> It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 f.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 f.2d 274, 276-277, 126 USPQ 186, 188 (ccpa 1960). As this court explained in Crockett, the idea of combining them flows logically from their having been individually taught in the prior art.

In this application it would have been prima facie obvious to combine Etopside composition, above and polypeptide conjointly to treat cancer.

For the reasons above, the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

No claim is allowed.

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is (703) 308-2232. The examiner can normally be reached on Monday through Friday from 9 AM. to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Theodore J. Criares
Primary Examiner
Art Unit 1617

jmk
August 20, 2001